

16022195

AUG 07 2002

**Section 3**  
**Coamatic® AT-400 - 510(k) Summary**  
**(Summary of Safety and Effectiveness)**

**Submitted by:**

Instrumentation Laboratory Company  
113 Hartwell Avenue  
Lexington, MA 02421  
Phone: 781-861-4467  
Fax: 781-861-4207

**Contact Person:**

Carol Marble, Regulatory Affairs Manager  
Phone: 781-861-4467 / Fax: 781-861-4207

**Summary Prepared:**

July 3, 2002

**Name of the Device:**

Coamatic® AT-400

**Classification Name(s):**

864.7060	Antithrombin III Assay	Class II
81JBQ	Antithrombin III Quantitation	

**Identification of Predicate Device(s):**

K980499 IL Test™ Antithrombin

**Description of the Device/Intended use(s):**

Coamatic® AT-400 is intended for the quantitative determination of the heparin cofactor activity of antithrombin (AT) in human citrated plasma.

Antithrombin is the most important natural inhibitor of the coagulation cascade. By inhibiting the coagulation proteases, especially thrombin, factor Xa and factor IXa, antithrombin prevents uncontrolled coagulation and thrombosis. Plasma is incubated with an excess of Factor Xa (FXa) in the presence of heparin. The residual activity of FXa is determined by the rate of hydrolysis of the chromogenic substrate S-2772. The pNA release measured at 405 nm is inversely proportional to the AT level in the range 10-125% of normal plasma.

**Statement of Technological Characteristics of the Device Compared to Predicate Device:**

Coamatic® AT-400 is substantially equivalent in performance to the predicate device: IL Test™ Antithrombin

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**Summary of Performance Data:**

**Method Comparison**

In a method comparison study evaluating 61 citrated plasma samples with Antithrombin levels ranging in value from 10.4 to 125% AT activity, the correlation statistics for Coamatic® AT-400 on an ACL Futura versus the predicate device on an ACL 9000 are shown below:

<b>System</b>	<b>Slope</b>	<b>Intercept</b>	<b>r</b>	<b>Reference Method</b>
ACL Futura	0.9810	4.9773	0.995	IL Test™ Antithrombin on ACL 9000

**Precision**

Within run and total precision assessed over multiple runs using three levels of control plasma gave the following results:

<b>ACL Futura</b>				
<b>Mean (% AT)</b>	<b>CV% (Within run)</b>	<b>n</b>	<b>CV% (Total)</b>	<b>n</b>
113	1.80	6	2.81	60
59	2.64	6	3.23	60
31	4.52	6	4.76	60



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

AUG 07 2002

Ms. Carol Marble  
Regulatory Affairs Manager  
Instrumentation Laboratory Company  
101 Hartwell Avenue  
Lexington, Massachusetts 02421-3125

Re: k022195  
Trade/Device Name: Coamatic® AT-400  
Regulation Number: 21 CFR § 864.7060  
Regulation Name: Antithrombin III Assay  
Regulatory Class: II  
Product Code: JBQ  
Dated: July 3, 2002  
Received: July 5, 2002

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

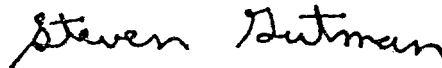
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K022195

Device Name: Coamatic® AT-400

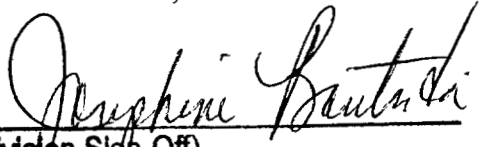
### Indications for Use:

Coamatic® AT-400 is intended for the quantitative determination of the heparin cofactor activity of antithrombin (AT) in human citrated plasma.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K022195

Prescription Use ☒  
(Per 21 CFR 801.019)

OR Over-The-Counter Use ☐